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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,996	05/24/2000	Mark T. Keating	408-916010US	4041

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EXAMINER	
CHEN, SHIN LIN	
ART UNIT	**PAPER NUMBER**
1633	5

DATE MAILED: 12/26/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/554,996	Applicant(s) KEATING ET AL.	
	Examiner Shin-Lin Chen	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-47* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 6-14, 22-24, 26-35 and 39, drawn to a pharmaceutical composition that provides an elastin-based composition comprising polypeptide or peptide of elastins, tropoelastins, or fragment thereof and a method for prophylaxis or treatment of a disorder of diminished capacity to regulate smooth muscle cell function by delivering said elastin-based composition.

Group II, claim(s) 5 and 25, drawn to a pharmaceutical composition that provides an elastin-based composition comprising an expression vector encoding a tropoelastin or a fragment thereof, and a method for prophylaxis or treatment of a disorder of diminished capacity to regulate smooth muscle cell function by delivering said elastin-based composition.

Group III, claim(s) 15-21, drawn to a method of producing an elastin-based composition by treating blood vessel with denaturing detergent followed by alkaline solution and a method for preparing a biocompatible support comprising an elastin-based composition.

Group IV, claim(s) 1, 22 and 36-38, drawn to a pharmaceutical composition that provides an elastin-based composition comprising one or more elastic fiber, and a method for prophylaxis or treatment of a disorder of diminished capacity to regulate smooth muscle cell function by

delivering said elastin-based composition, wherein said pharmaceutical composition is a tubular elastin based composition as an artificial blood vessel.

Group V, claim(s) 40-42, drawn to a method for prophylaxis or treatment of a disorder of diminished capacity to regulate smooth muscle cell function, such as SVAS or hypertension, by administering an elastase inhibitor to an individual.

Group VI, claim(s) 43 and 44, drawn to a method to screen for a drug candidate useful in the prophylaxis or treatment of a disorder of a diminished capacity to regulate smooth muscle cell function, such as atherosclerosis, SVAS, or hypertension, comprising administering a drug to an ELN +/- or ELN -/- organism or cell and determine the increase of elastin mRNA by measuring synthesis of elastin RNA.

Group VII, claim(s) 43 and 45, drawn to a method to screen for a drug candidate useful in the prophylaxis or treatment of a disorder of a diminished capacity to regulate smooth muscle cell function, such as atherosclerosis, SVAS, or hypertension, comprising administering a drug to an ELN +/- or ELN -/- organism or cell and determine the increase of elastin protein level by measuring synthesis of elastin protein.

Group VIII, claim(s) 43 and 46, drawn to a method to screen for a drug candidate useful in the prophylaxis or treatment of a disorder of a diminished capacity to regulate smooth muscle cell function, such as atherosclerosis, SVAS, or hypertension, comprising administering a drug to an ELN +/- or ELN -/- organism or cell and determine the increase of elastin activity by measuring activity of elastase.

Group IX, claim(s) 43 and 47, drawn to a method to screen for a drug candidate useful in the prophylaxis or treatment of a disorder of a diminished capacity to regulate smooth muscle cell function, such as atherosclerosis, transplant arteriopathy, or restenosis, comprising administering a drug to an ELN -/- organism or cell and measuring inhibition of vascular smooth muscle cell (VSMC) proliferation, stimulation of VSMC differentiation, or regulation of VSMC migration.

Claims 1 and 22 link(s) groups I and IV. Claim 43 links inventions VI-IX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 22 and 43. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also M.E.P.. § 804.01.

2. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Inventions I, II, IV and V are not related. Raju et al., 1987 (The Journal of Biological Chemistry, Vol. 262, p. 5755-5762) discloses the cDNA sequence encoding bovine elastin (e.g. p. 5757) and Fazio et al., 1988 (Laboratory Investigation, Vol. 58, p. 270-277) discloses the cDNA sequence encoding human elastin and elastin gene expression in cultured skin fibroblasts (e.g. title, p. 272). Thus, no special technical feature that contributes over the prior art has been provided. Further, inventions I, II, IV and V are drawn to different pharmaceutical compositions or methods using different materials having different chemical structures, different physical properties and different biological functions: polypeptides or peptides, expression vectors or nucleic acids, elastic fibers, and elastase inhibitors. They are materially different methods which differ at least in process steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. They are different methods that do not share special technical feature.

Similarly, invention III is not related to inventions I-II and IV-V. They are drawn to materially different methods which differ in objectives, process steps, reagents and/or dosages used, schedules used, response variables, and criteria for success.

Inventions VI-IX are not related. They are drawn to different methods having different process steps: measuring synthesis of elastin RNA, measuring synthesis of elastin protein, measuring the activity of elastase, and measuring inhibition of vascular smooth muscle cell

(VSMC) proliferation, stimulation of VSMC differentiation, or regulation of VSMC migration. They require the use of different reagents and/or dosages, schedules and responsive variables. They are different methods that do not share common special technical feature. Similarly, inventions I-V are not related to inventions VI-IX. They are drawn to materially different methods which differ in objectives, process steps, reagents and/or dosages used, schedules used, response variables, and criteria for success. Thus, inventions I-IX do not relate to a single general inventive concept under PCT Rule 13.1.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, whose telephone number is (703) 305-3015.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.